

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION**

Alliance for Hippocratic Medicine, *et al.*,

Plaintiffs,

v.

Case No. 2:22-cv-00223-Z

U.S. Food and Drug Administration, *et al.*,

Defendants,

and

Danco Laboratories, LLC,

Intervenor-Defendant.

**Defendants' Reply Memorandum in Support of Their Motion to Hold in Abeyance the
Motion to Intervene filed by States of Missouri, Kansas, and Idaho**

The States of Missouri, Kansas, and Idaho have sought to intervene in this case almost a year after it was filed, while the case is currently pending before the Supreme Court. The States' motion is for the express purpose of remedying jurisdictional defects in Plaintiffs' standing, which Defendants have highlighted for the past ten months. Of course, neither the States nor Plaintiffs concede that any standing defects currently exist—indeed, they continue to argue the opposite—but they nonetheless demand urgent action from this Court on the States' intervention request.

Rather than accept the States' invitation to inject new issues into this case while it is currently pending before the Supreme Court, this Court should instead await the conclusion of those Supreme Court proceedings before determining how best to proceed on the intervention motion. The States' opposition to this abeyance request, *see* ECF No. 156, does not dispute that resolution of the Supreme Court proceedings could, in at least some circumstances, affect this Court's analysis of their intervention motion—including by determining whether any further proceedings in this Court are even necessary. Nor do the States offer any concrete reason *why* it is imperative for this Court to decide their intervention motion now, despite proceedings in this Court presently being stayed, and particularly given that granting intervention would not by itself entitle the States to participate in the already-pending proceedings before the Supreme Court—let alone alter the scope of issues potentially pending before that Court.

The most prudent course is thus to hold the intervention motion in abeyance pending resolution of the Supreme Court proceedings. In the alternative, the United States respectfully requests a reasonable amount of time to respond to the States' unanticipated intervention motion—*i.e.*, 30 days from denial of this abeyance request. By the States' own admission, they took at least several months to prepare their intervention request, which by itself highlights that there is no need for urgent action on their intervention request. And they do not even attempt to articulate a need for a decision on their motion by any particular date.

At a minimum, if this Court is not inclined to grant the United States' primary forms of requested relief, consistent with the States' agreement that "a reasonable extension past the Thanksgiving holiday" is appropriate, ECF No. 156 at 9, Defendants respectfully request that the

Court extend their current deadline from Friday, November 24 (the day after Thanksgiving) by at least ten days to Monday, December 4, 2023, to avoid a conflict with the upcoming holiday and to allow adequate time for Defendants to respond to the numerous issues raised by the States' request.

Discussion

I. Awaiting Resolution of the Pending Supreme Court Proceedings Before Deciding Intervention Is the Most Prudent Course

As discussed more fully in Defendants' opening motion, resolution of the pending Supreme Court proceedings pertaining to this Court's April 7, 2023 Order could eliminate the need for this Court to consider the States' intervention motion at all, or at least could affect this Court's analysis of that motion. *See* ECF No. 155 at 3-6. None of the States' responses alters that conclusion.

1. The States initially portray the United States' abeyance request as "rest[ing] on three speculative assumptions," namely that "(1) the Supreme Court might grant their petition for certiorari, (2) the Supreme Court might rule in their favor on standing, and (3) the Supreme Court might not consider the standing of the States." ECF No. 156 at 2. According to the States, resolution of the intervention motion by this Court would be unnecessary only "[i]f the Supreme Court does all three of these things." *Id.*

As an initial matter, the States take an unduly narrow view of Defendants' abeyance motion. The rationale supporting Defendants' abeyance request is not limited to only those scenarios where the Supreme Court concludes that Plaintiffs lack standing. Even if the Supreme Court concludes that Plaintiffs have adequately established their standing, there are other ways in which a decision from the Supreme Court could eliminate the need for this Court to consider (or at least affect this Court's consideration of) the States' intervention motion—*e.g.*, if the Supreme Court opines on other threshold issues such as statute of limitations, or resolves the merits of Plaintiffs' claims in a way that makes further proceedings in this Court unnecessary. *See* ECF No. 155 at 5-6. In these scenarios, consideration of the States' intervention motion now would be inefficient, because that litigation may prove wholly unnecessary or subject to re-evaluation following a Supreme Court decision in this matter. There are countless ways in which litigating a

potentially unnecessary motion now, while the legal landscape is in flux, would be inefficient—beyond just the possibility that the Supreme Court might determine that Plaintiffs lack standing.

In any event, none of the States’ supposedly “speculative assumptions” justifies denying abeyance. Starting with the first two, the States assert that it is “speculative” whether “the Supreme Court might grant [Defendants’] petition for certiorari” and “rule in their favor on standing.” ECF No. 156 at 2. Of course, this argument is difficult to square with the very premise of the States’ intervention motion, which is that the Court may well “agree[] with the Federal Government’s standing arguments.” ECF No. 152 at 5. Additionally, the Supreme Court previously granted a stay of this Court’s April 7 Order, *see Danco Lab’ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023); two of the criteria for granting such relief are that there must be “a reasonable probability that [the Supreme] Court would eventually grant review” and that there is “a fair prospect that the [Supreme] Court would reverse” the decision under review. *Merrill v. Milligan*, 142 S. Ct. 879, 880 (2022) (Kavanaugh, J., concurring). At least as to the first assumption, then, the Court itself has entered relief suggesting that granting certiorari is not speculative. Regardless, if the States’ argument is correct—*i.e.*, that there is a meaningful chance the Supreme Court might deny the petitions for certiorari or conclude that the existing Plaintiffs do have standing—that only confirms abeyance is the appropriate course. In either of those scenarios, the States could not plausibly be prejudiced by holding their intervention motion in abeyance pending those outcomes.

On the third assumption—that the Supreme Court will not address the States’ own Article III standing—the States offer no basis to think that the Supreme Court *would* address their standing. As discussed below, if Plaintiffs lack standing to initiate this suit, that would be the end of the case regardless of the States’ standing; there thus would be no basis for the Supreme Court to discuss the States’ purported standing as part of its review of this Court’s April 7 Order.

Moreover, even if this Court were to grant the States’ intervention motion, that would not make the States parties to the already-pending Supreme Court proceedings regarding this Court’s April 7 Order, *see* ECF No. 155 at 6 n.1, which is a point that the States do not dispute. The parties to a case in the Supreme Court are the “parties to the proceeding *in the court whose judgment is*

sought to be reviewed”—here, the Fifth Circuit appeal. Supreme Court Rule 12.6 (emphasis added). An order granting the States’ motion to intervene for purposes of future proceedings in this Court would not retroactively make them parties to the already-completed appeal in the Fifth Circuit and thus would not give them party status in the Supreme Court. Nor do the States identify any other basis for the Supreme Court to consider their standing. The Supreme Court is “a court of review, not of first view,” *Cutter v. Wilkinson*, 544 U.S. 709, 719 n.7 (2005), but the States’ theories of injury were not before the Fifth Circuit. And the States do not point to anything in the Questions Presented or elsewhere in the petitions for certiorari suggesting that the States’ standing claims would be at issue if the Supreme Court agrees to review the Fifth Circuit’s judgment. Thus, the States’ own claimed standing would not be properly before the Supreme Court regardless of how this Court decides intervention—highlighting that there is no reason to decide it now, prior to conclusion of the Supreme Court proceedings. The States’ suggestion that granting intervention now would allow the Supreme Court to “fully resolve the merits” of the underlying dispute even if the Plaintiffs lack standing, ECF No. 156 at 1, fails because intervention in this Court would not make the States parties to those proceedings or otherwise place their standing before the Court.

2. The States also maintain that, even if the Supreme Court determines that Plaintiffs lack Article III standing, the States’ intervention could save this case from dismissal based on the States’ own Article III injuries. Specifically, the States contend that as long as this Court grants intervention *prior* to a dismissal order, their intervention remains valid regardless of any later determination by the Supreme Court that Plaintiffs lacked standing to bring the suit. *See* ECF No. 156 at 3-4. But this argument is contrary to fundamental principles of jurisdiction.

“Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCordle*, 7 Wall. 506, 514 (1868)). Because this requirement “springs from the nature and limits of the judicial power of the United States, [it] is inflexible and without exception.” *Id.* at 94-95. Here, if the Supreme Court determines that Plaintiffs lacked

Article III standing to initiate this suit, then “the only function remaining to [this] court is that of announcing the fact and dismissing the cause.” *Id.* at 94. The States’ intervention in the case cannot create jurisdiction if the Supreme Court determines that Article III jurisdiction over the case did not exist at the outset. And that remains true regardless of whether lower courts erroneously thought that jurisdiction existed at the time they granted the States’ request for intervention.

This principle follows from the cases cited in the abeyance motion, *see* ECF No. 155 at 4, which the States fail to meaningfully distinguish. The States wholly ignore *Disability Advocs., Inc. v. New York Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149 (2d Cir. 2012), in which the Second Circuit held that intervention could not save a suit from dismissal when the original plaintiffs lacked standing, even though the district court granted intervention at a time when it believed jurisdiction existed—a result squarely at odds with the States’ theory here. *Id.* at 155, 160-62. The States contend that *Mattice v. Meyer*, 353 F.2d 316 (8th Cir. 1965), held only “that ‘there was no basis for intervention’ when the original suit had already been dismissed,” ECF No. 156 at 4, but that is inaccurate—the motion to intervene was filed *before* the case was dismissed, *see* 353 F.2d at 317, and the Eighth Circuit upheld the denial of intervention solely because the original plaintiff lacked standing, without considering whether the putative intervenor would have independently had standing, *id.* at 319. And although it is true that *United States ex rel. Texas Portland Cement Co. v. McCord*, 233 U.S. 157 (1914), involved a statutory bar on an action being filed at a particular time, *see* ECF No. 156 at 4, the States do not explain why a statutory bar is an absolute barrier that cannot be fixed by an intervenor with a then-proper claim, but a lack of subject-matter jurisdiction *can* be fixed through intervention. If anything, a lack of jurisdiction should be a *greater* impediment to continuing the case than a statutory limitation on the underlying cause of action.¹

¹ The States also contend that *Fuller v. Volk*, 351 F.2d 323 (3d Cir. 1965), supports their intervention, because in that case the intervenor was allowed to continue with their claims despite the original plaintiff lacking jurisdiction. *See* ECF No. 156 at 4-5. But the court treated the intervenor’s claims “as a separate action,” 351 F.2d at 328, which courts have discretion to do only

Moreover, these cases are far from the only ones holding that addition of a new party cannot save a case from dismissal if the case was not jurisdictionally proper at the outset. In *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995), the Fifth Circuit expressly held that Rule 15 could not be used to fix a jurisdictional defect by substituting a new party *regardless* of whether the Rule 15 request was made before dismissal: “In short, regardless of when the district court actually determines it lacks subject matter jurisdiction over the original plaintiff, Rule 15 does not allow a party to amend to create jurisdiction where none actually existed.” *Id.* at 453 (cleaned up). That holding is directly contrary to the States’ theory, which posits that jurisdiction can be rectified at any point prior to an actual order of dismissal. *See also, e.g., Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 776 (5th Cir. 1986) (“The citizenship of a party at the *commencement* of the action is controlling for purposes of determining diversity jurisdiction and subsequent actions do not affect the court’s jurisdiction. Jurisdiction cannot be created retroactively by substituting a diverse claimant for a nondiverse party.” (citations omitted)); *Summit Off. Park, Inc. v. U.S. Steel Corp.*, 639 F.2d 1278, 1282 (5th Cir. 1981); *Oklahoma Firefighters Pension & Ret. Sys. v. Six Flags Ent. Corp.*, --- F. Supp. 3d ----, 2023 WL 3781645, at *6 (N.D. Tex. June 2, 2023). The lone precedent cited by the States in support of their theory—that intervention can keep a case alive despite the case being jurisdictionally defective at the outset—is a decision from the Seventh Circuit, stating that “intervention is ‘judged as of the time the motion [i]s ruled upon.’” ECF No. 156 at 3 (quoting *Equal Empl. Opportunity Comm’n v. United Air Lines, Inc.*, 515 F.2d 946, 950 (7th Cir. 1975)). But that statement was made in the context of evaluating Rule 24’s timeliness factor; that statement had nothing to do with the jurisdictional prerequisites for intervention.

In short, then, the States have failed to meaningfully dispute the “deeply entrenched” principle that “intervention will not be permitted to breathe life into a ‘nonexistent’ law suit.” *Disability Advocs., Inc.*, 675 F.3d at 160. This principle underscores why holding the intervention

when the intervenor would independently satisfy both jurisdiction and venue, as Defendants previously explained. *See* ECF No. 155 at 4-5. The States plainly cannot satisfy venue here, which precludes adjudication of their claims if Plaintiffs lack standing, as addressed further below.

motion in abeyance is the most prudent course here—because if the Supreme Court agrees that Plaintiffs lack Article III standing, this suit must be dismissed, which would obviate the need for this Court ever to decide the States’ intervention motion.

3. The States also argue that holding their intervention motion in abeyance would lead to “senseless delay” because, even if the Supreme Court agrees that the current Plaintiffs lack standing, the States will still find a way to present their claims to this Court. Specifically, the States offer various hypothetical scenarios they might pursue, such as filing a new complaint alongside the current Plaintiffs, or perhaps filing their own complaint and then arguing that exhaustion and venue requirements should be excused. *See* ECF No. 156 at 5-7. As an initial matter, these hypothetical scenarios only further emphasize that abeyance is the most prudent course. It makes little sense for this Court to decide these intervention issues now, based on predictions about how the Court might rule on hypothetical future complaints involving different potential groups of plaintiffs. The far more pragmatic course is to await the resolution of the pending Supreme Court proceedings, and then address whatever issues (if any) actually require resolution at that time.

Regardless, the States’ theories are also wrong. The States claim that even “[i]f the Supreme Court ruled against the private plaintiffs on standing,” the “States and private plaintiffs could file a new, joint complaint relying on the ‘one plaintiff’ rule for standing.” ECF No. 156 at 5. But that is a significant distortion of the “one plaintiff” rule, which generally provides that if a court determines one plaintiff has standing, the court need not consider the standing of other plaintiffs seeking the same relief. *See, e.g., Biden v. Nebraska*, 143 S. Ct. 2355, 2365 (2023). That principle does not equate to what the States are attempting here, which is retaining the existing Plaintiffs as parties even after the Supreme Court has affirmatively determined those Plaintiffs *not* to have standing, for the express purpose of satisfying venue and exhaustion requirements that would otherwise bar the States’ own claims. *See* ECF No. 156 at 6-7. Once a plaintiff is determined to lack standing, that plaintiff must be dismissed from the case even if other plaintiffs do have standing. *See, e.g., TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021) (“Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not.”);

Summers v. Earth Island Inst., 555 U.S. 488, 494-97 (2009) (although one plaintiff had standing for a claim, other plaintiffs lacked standing and must be dismissed); *Doe v. Cnty. of Montgomery*, 41 F.3d 1156, 1161-62 & n.4 (7th Cir. 1994). The States cite nothing in support of their novel theory that, even after the Supreme Court determines a party lacks standing, that party is allowed to remain in the case based on someone else’s standing—let alone that the party can remain in the case *and* be used to overcome otherwise valid defenses to the remaining claims.

As explained previously, the States themselves cannot satisfy venue given that none resides in this District—a point that the States do not contest. *See* ECF No. 155 at 4-5. Consistent with the above principles, then, the States cannot eliminate this venue problem simply by appending additional plaintiffs to their complaint who themselves plainly lack standing (or who have already been determined by the Supreme Court to lack standing). Indeed, courts routinely reject such attempts to manufacture venue. *See, e.g., Miller v. Albright*, 523 U.S. 420, 426–27 (1998) (op. of Stevens, J.) (“[T]he District Court concluded that Mr. Miller did not have standing and dismissed him as a party. Because venue in Texas was therefore improper, see 28 U.S.C. § 1391(e), the court transferred the case[.]”); *Inst. of Certified Pracs., Inc. v. Bentsen*, 874 F. Supp. 1370, 1372 (N.D. Ga. 1994); *Nat’l Distillers & Chem. Corp. v. Dep’t of Energy*, 487 F. Supp. 34, 36-37 (D. Del. 1980); Wright & Miller, *Federal Practice & Procedure* § 3815 (4th ed. Apr. 2023).

The States suggest that “venue is not jurisdictional,” and therefore this Court could elect to “maintain the action . . . even if venue would have been improper had the States brought this suit on their own at the outset.” ECF No. 156 at 7. But the States cite nothing to support their argument that a court can refuse to act on a timely raised venue objection; their only statutory citation speaks to waiver. *See* 28 U.S.C. § 1406(b). And the relevant statutory subsection speaks in mandatory terms regarding dismissal or transfer in the face of a timely venue objection. *Id.* § 1406(a).²

² The States’ quoted passage from Wright & Miller, *see* ECF No. 156 at 7, is discussing intervenors’ claims in a case that independently satisfied jurisdiction. If the original action has been dismissed for lack of jurisdiction, then intervenors’ claims may proceed only “as if it were a separate suit . . . [that] satisfies *by itself* the requirements of jurisdiction and venue.” Wright & Miller, *Federal Practice & Procedure*, § 1918 (4th ed. Apr. 2023) (emphasis added).

Finally, the States also contend that even if they were forced to bring claims on their own, the statute of limitations and exhaustion defenses would not pose an impediment. *See* ECF No. 156 at 5-6 & n.2. These arguments only further emphasize the degree to which the States' intervention motion is wrapped up in potential merits issues and this Court thus should await resolution of the Supreme Court proceedings before considering intervention.

4. Lastly, the States do not offer any cognizable theory of prejudice that would flow from holding their intervention motion in abeyance pending resolution of the Supreme Court proceedings. The States generally argue that doing so could result in unnecessary delay, *see* ECF No. 156 at 7-8, but all of the States' arguments presuppose that, if intervention is allowed, that would somehow affect the ongoing Supreme Court proceedings and that Court's consideration of Plaintiffs' standing. As discussed above, that assumption is incorrect—resolving the States' intervention motion now has no effect on the ongoing Supreme Court proceedings.

In contrast, holding the intervention motion in abeyance pending resolution of the Supreme Court proceedings would plainly be the most efficient course for the parties and this Court. Doing so would avoid litigation and decision on a motion that is potentially unnecessary depending on how the Supreme Court proceedings are resolved. And even if litigation over the States' intervention request is ultimately necessary, both the parties and this Court will be in a far better position to evaluate that motion with the benefit of any ruling from the Supreme Court regarding this Court's April 7 Order. Thus, the most prudent course is to hold the intervention motion in abeyance pending resolution of the Supreme Court proceedings.

II. Alternatively, Defendants Should Be Afforded Additional Time to Respond to the Intervention Motion

By the States' own account, they intended to intervene in this action at least as of July or August 2023. *See* ECF No. 152 at 3-4; ECF No. 156 at 8 n.4. Yet they waited until November 3, 2023 to file their motion. *See* ECF No. 151 at 1. During those several months, the States “identif[ied] and retain[ed] experts, locate[d] relevant agency data, [and] obtain[ed] declarations” to support their claims. ECF No. 156 at 10. Despite having taken several months to prepare their

filing and supporting materials, the States now oppose Defendants’ request for an additional 30 days after this Court rules on the abeyance request.

Notably, the States offer no explanation whatsoever for how the requested 30-day extension could conceivably prejudice them. The States do not identify any need for urgent action on by a particular date, and their own actions—taking months to prepare their request—confirm there is no urgency. That alone should be enough to warrant granting Defendants’ alternate request.

The States imply that Defendants overstated the volume of new materials attached to the States’ intervention motion. ECF No. 156 at 9-10. But the reason Defendants are requesting this additional time is precisely so that they have a full opportunity to review the submitted materials and evaluate them in light of what has been previously filed in this case. Although the States assert that “the only new material relates to State standing” and “the complaint presses no new substantive claims,” ECF No. 156 at 9, Defendants should be afforded sufficient time to make that determination for themselves. Already, Defendants’ preliminary review suggests there are at least some differences between the complaints, given that the States seek to challenge certain FDA actions taken in 2023, *see* ECF No. 151-1 ¶¶ 423-27, which are not challenged in Plaintiffs’ complaint and which Plaintiffs have not sought leave to file a supplemental complaint to challenge. *See* Fed. R. Civ. P. 15(d). Moreover, even if the States’ supporting appendix contains only six new exhibits, those six exhibits purport to cover a wide variety of topics—and Defendants’ request for approximately 30 additional days to review and prepare a response to these materials is reasonable, particularly given the unexpected nature of the States’ motion at this point in the case.

At an absolute minimum, even if the Court is not inclined to grant either of Defendants’ primary forms of requested relief, given that Defendants’ opposition is currently due on Friday, November 24 (the day after Thanksgiving)—and given that the States do not oppose “a reasonable extension past the Thanksgiving holiday,” ECF No. 156 at 9—Defendants respectfully request that their opposition deadline be extended at least ten days until December 4, 2023, to avoid any conflict with the upcoming Thanksgiving holiday and allow time for a fulsome response.

November 16, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel

JULIE STRAUS HARRIS
ERIC B. BECKENHAUER
Assistant Directors

MARK RAZA
Associate General Counsel
U.S. Department of Health
and Human Services
Chief Counsel
Food and Drug Administration

DANIEL SCHWEI
Special Counsel

/s/ Kate Talmor
KATE TALMOR
CHRISTOPHER A. EISWERTH
EMILY NESTLER
Trial Attorneys
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
202-305-8693
kate.talmor@usdoj.gov

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Acting Director

HILARY K. PERKINS
Assistant Director

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch